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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

WARNING LETTER

September 13, 1999
Certified Mail
Return Receipt Requested

99-SWR-WL-21/0

Keith Vrbicky, M.D.
Midwest Health Partners, P.C.
1410 N. 13th Street
P.O. Box 209
Norfolk, NE 68702

RE: Inspection ID - 1256170005

Dear Keith Vrbicky, M.D.,

We are writing to you because on 09/01/1999, your facility was inspected by a representative of the State of NE, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and level 2 findings at your facility:

Level 1: Mammograms were processed in processor (1), Kodak, RP X-OMAT M3W, when it was out of limits on 5 days.

Level 2 Repeat: Processor QC records were missing 3 out of 22 days of operation in month 07/1999. Processor QC records missing 14%, for processor (1), Kodak, RP X-OMAT M3.

Level 2: There is no written procedure for handling consumer complaints.

There is no written procedure for infection control.

Corrective actions for processor QC failures were not documented at least once for processor (1), Kodak, RP X-OMAT M3.

Processor QC records were missing 3 consecutive days for processor (1), Kodak, RP X-OMAT M3.

Corrective action for a failing image score (before further exams) was not documented for Bennett X-Ray unit.

Phantom QC records were missing for at least two weeks but less than four weeks for Bennett X-Ray unit.

5 of 5 random reports reviewed did not contain an assessment category.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

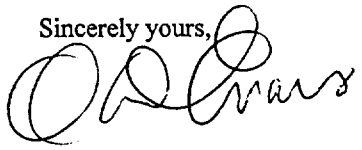
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:
Deborah M. McGee
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 ext. 138 or fax (214) 655-8130.

Sincerely yours,



for Edward R. Esparza
Regional Food and Drug Director